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EXPRESS MAIL CERTIFICATE

Date: 11/8/02 Label No. EV 208554045-US

I hereby certify that, on the date indicated above, this paper or fee was deposited with the U.S. Postal Service & that it was addressed for delivery to the Assistant Commissioner for Patents, Washington, DC 20231 by "Express Mail Post Office to Addressee" service.

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D. Davis  
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PATENT TRADEMARK OFFICE

Docket No.: 6727/OK322

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Yoav BLATT; Oded ARAD; Eugene KIMELMAN; David COHEN; Rivka PINTO; Avner ROTMAN

Serial No.: 10/069,388

Filed: June 28, 2002

For: MICROENCAPSULATED AND CONTROLLED-RELEASE  
FORMULATIONS OF ISOFLAVONE FROM ENRICHED FRACTIONS OF  
SOY AND OTHER PLANTS

November 8, 2002

INFORMATION DISCLOSURE STATEMENT

Hon. Commissioner of  
Patents and Trademarks  
Washington, DC 20231

Sir:

This Information Disclosure Statement is submitted in accordance with  
37 C.F.R. 1.97, 1.98, and it is requested that the information set forth in this  
statement and in the listed documents be considered during the pendency of the

above-identified application, and any other application relying on the filing date of the above-identified application or cross-referencing it as a related application.

1. This IDS should be considered, in accordance with 37 C.F.R. 1.97, as it is filed: (Check one of the boxes A-D)

- ☐ A. Within three months of the filing date of the above-identified national application or within three months of the entry into the national stage of the above-identified international application.
- ☒ B. before the mailing date of a first office action on the merits, or a first office action after filing a request for continued examination.
- ☐ C. after (A) and (B) above, but before the mailing date of a final rejection, a notice of allowance, or any other action that closes prosecution, and Applicants have made the necessary statement in box "i" below or paid the necessary fee in box "ii" below.

(check one of the boxes "i" and "ii" below:)

- ☐ i. Counsel states that, upon information and belief, each item of information listed herein was either (a) cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS; or (b) was not cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of undersigned after making reasonable inquiry, was not known to any individual designated in 1.56(c) more than three months prior to the filing of this IDS.
- ☐ ii. A check for the fee set forth in 1. 17(p), presently believed to be \$180, is enclosed.
- ☐ D. after (A), (B) and (C) above, but before payment of the issue fee: Counsel states that, upon information and belief, each item of information listed herein was either (i) cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the IDS; or (ii) was not cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of the undersigned after making reasonable inquiry, was not known to any individual designated in 1.56(c) more than three months prior to the filing of this IDS.
  - ☐ i. A check for the fee set forth in 1.17 (p), presently believed to be \$180, is enclosed.

2. In accordance with 37 C.F.R. 1.98, this IDS includes a list (e.g., form

PTO-1449) of all patents, publications, or other information submitted for consideration by the office, either incorporated into this IDS or as an attachment hereto. A copy of each document listed is attached, except as explained below.

(check boxes A and/or B and fill in blanks, if appropriate.)

- ☐ A. Document(s) \_\_\_\_\_ is (are) deemed substantially cumulative to document(s) \_\_\_\_\_, and, in accordance with 1.98(c), only a copy of each of the latter documents is enclosed.
- ☐ B. Certain documents were previously cited by or submitted to the Office in the following prior applications, which are relied upon under 35 U.S.C. 120:

[SERIAL NO. & FILING DATE].

Applicant Identifies these documents by attaching hereto copies of the forms PTO-892 and PTO- 1449 from the files of the prior application(s) or a fresh PTO- 1449 listing these documents, and request that they be considered and made of record in accordance with 1.98(d). Per 37 CFR 1.98(d), copies of these documents need not be filed in this application.

☐ 3. Document Nos. \_\_\_\_\_ are not in the English language. In accordance with 1.98(c), Applicant states:

- ☐ An English translation of each document (or of the pertinent portions thereof), or a copy of each corresponding English-language patent or application is enclosed.
- ☐ A concise explanation of the relevance of document(s) \_\_\_\_\_ is found in the attached search report (see MPEP § 609 A(3)x).
- ☐ A concise explanation of the relevance of document(s) \_\_\_\_\_ is set forth as follows: [Insert concise explanation of relevance]
- ☐ A concise explanation of the relevance of document(s) \_\_\_\_\_ can be found on pages \_\_\_\_\_ of the specification.
- ☐ A concise explanation of document(s) \_\_\_\_\_ can be found on the attached sheet.

☐ 4. No explanation of relevance is necessary for documents in the English

language (see MPEP § 609 A(3)).

[] 5. Other information being provided for the examiner's consideration follows:

6. In accordance with 37 C.F.R. 1.97(g) and (h), the filing of this IDS should not be construed as a representation that a search has been made or that information cited is, or is considered to be, material to patentability as defined in §1.56 (b), or that any cited document listed or attached is (or constitutes) prior art. Unless other-wise indicated, the date of publication indicated for an item is taken from the face of' the item and Applicant reserves the right to prove that the date of publication is in fact different.

**CROSS REFERENCE UNDER 37 C.F.R. §1.78 TO RELATED APPLICATIONS**

Pursuant to 37 C.F.R. § 1.78, Applicant notes that the above-identified patent application may be related to the following U.S. Patent Applications:

(1) U.S. Patent Application Serial No \_\_\_\_\_, filed \_\_\_\_\_.

Early and favorable consideration is earnestly solicited.

Respectfully submitted,



S. Peter Ludwig  
Registration No. 25,351  
Attorney for Applicant(s)

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Docket No. 6727/0K322



FORM PTO-1449

U.S. DEPARTMENT OF COMMERCE PATENT &amp; TRADEMARK OFFICE

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NOV 14 2002  
SHEET 1 OF 1  
(REV. 1-80)  
TECH CENTER 1600/25000

**LIST OF REFERENCES CITED BY APPLICANT**

(Use Several Sheets if Necessary)

DOCKET NO.: 6727/OK322 SERIAL NO: 10/069,388  
APPLICANT: Yoav BLATT et al. FILING DATE: June 28, 2002

**U.S. PATENT DOCUMENTS**

<u>*EXAMINER INITIALS</u>	<u>DOCUMENT NUMBER</u>	<u>DATE</u>	<u>NAME</u>	<u>CLASS</u>	<u>SUBCLASS</u>	<u>FILING DATE</u>
	1. 5,780,060	Jul. 1998	Levy et al.	424	489	
	2. 6,004,558	Dec. 1999	Thurn et al.	424	195.1	
	3. 5,707,353	Jan. 1998	Mazer	604	83	
	4. 4,708,874	Nov. 1987	De Haan et al.	424	470	
	5. 5,560,928	Oct. 1996	DeFelice	424	466	
	6. 5,985,282	Nov. 1999	Haveson	424	195.1	
	7. 6,340,478	Jan. 2002	Blatt et al.	424	489	

**FOREIGN PATENT DOCUMENTS**

<u>*EXAMINER INITIALS</u>	<u>DOCUMENT NUMBER</u>	<u>DATE</u>	<u>COUNTRY</u>	<u>CLASS</u>	<u>SUBCLASS</u>	<u>TRANSLATION YES NO</u>
	8. 00/20017	Apr. 2000	PCT	A61K	35/78	
	9. 00/30605	Jun. 2000	PCT	A61K	9/00	Abstract only
	10. 0702957	Dec. 1998	Europe	A61K	35/78	NO
	11. 0922450	Jun. 1999	Europe	A61K	9/20	NO

**OTHER REFERENCES****(INCLUDING AUTHOR, TITLE DATE, PERTINENT PAGES, ETC.)**

\*EXAMINER  
INITIALS

12. Bauer et al., Coated Pharmaceutical Dosage Forms. Fundamentals, Manufacturing Techniques, Biopharmaceutical Aspects, Test Methods and Raw Materials, CRC Press, Washington, D.C. 1998.
13. Remington's Pharmaceutical Sciences, 8th Edition, Mack Publishing Company, 1990, pp. 1288-1300.
14. Handbook of Pharmaceutical Excipients, pp. 81-90, 1986, by the American Pharmaceutical Association & Pharmaceutical Society of Great Britain.
15. USP 24, Test 786, pp. 1969-70.

EXAMINER: \_\_\_\_\_

DATE CONSIDERED: \_\_\_\_\_

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.